

REMARKS

Amendment to the Specification

The present amendment to the specification corrects certain typographical errors and, as discussed with respect to the drawings below, adds several new paragraphs to more clearly explain the invention. No new matter is introduced through these amendments.

Amendments to the Drawings

Figures 1-5 have been updated to formal drawings.

The drawings were objected to under 37 CFR 1.83(a) as not showing every feature of the invention specified in the claims. Fig. 4 has been amended to the specification and show how an indicator may be applied to housing 12 to show the proper orientation in which to apply housing 12 to the patient's body as previously discussed in paragraph 55. Figures 6-10 have been added to conform to the examiner's requests to show features of the invention described in claims 5, 8, 15, and 18-29. The specification has been amended to provide text referencing the newly added figures and the feature of Fig. 4. No new matter is introduced through these amendments.

Amendments to the Claims

1. Several claims have been amended. For the convenience of the examiner, an appendix is attached which shows all of the claims in their current state without editing mark-up.

2. Claims 6, 10, 15, 16, 41, and 45 were objected to because "superposition" was used. Said claims have been amended to use "superposed."

3. Claim 8 was objected to because "the superposition of the two axes" was used. Said claim has been amended to use "a superposition of the first and second axis."

4. Claim 9 was objected to because "the housing" was used. Said claim has been amended to use "a portion of the system."

5. Claims 15 and 16 were objected to because "body, are" was used. Said claims have been amended to use "body are."

6. Claims 15 and 16 were objected to because "tilt switches" was used. Said claims have been amended to use "gravity sensing switches."

7. Claim 16 was objected to because "the sensor" was used. Said claim has been amended by replacing "sensor indicates" with "gravity sensing switches indicate."

8. Claim 17 was objected to because "tilt switch" was used. Said claim has been amended to use "gravity sensing switch."

9. Claim 18 was objected to because "the superposition" was used. Said claim has been amended to use "a superposition."

Status of the Claims and General Summary of Claim Rejections

Claims 7-17 were rejected under 35 U.S.C. §101 because the claimed invention was directed to non-statutory subject matter.

Claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent No. 6,514,218 to Yamamoto (hereinafter referred to as Yamamoto).

Claims 1-4, 6-9, 12, 15, 17-19, and 29 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,263,491 to Thornton (hereinafter referred to as Thornton).

Claims 1, 2, 4, 5, 12-14, 17-19, 21, 25, and 30 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,275,159 to Griebel (hereinafter referred to as Griebel).

Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,241,683 to Macklem et al (hereinafter referred to as Macklem).

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,551,252 to Sackner et al (hereinafter referred to as Sackner).

Claims 24 and 52 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,432,061 to Nissila et al (hereinafter referred to as Nissila).

Claims 23, 26-28, and 51 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,168,568 to Gavriely (hereinafter referred to as Gavriely).

Claims 38 and 41-43 were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,171,258 to Karakasoglu et al (hereinafter referred to as Karakasoglu) in view of Thornton.

Claim 48 was rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,241,683 to Hatlesad (hereinafter referred to as Hatlesad).

35 U.S.C. § 101 Rejection

Claims 7-17 were rejected under 35 U.S.C. 101 because the claimed invention was directed to non-statutory subject matter as including the human body. Having amended claims 7, 8, 9, and 12 as suggested by the examiner to refer to, for example, “the portion of the patient’s body to which the system is adapted to be coupled” (claim 7), applicants respectfully request reconsideration of this rejection.

35 U.S.C. § 102(e) Rejections per Yamamoto

Claims 1, 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent No. 6,514,218 to Yamamoto (hereinafter referred to as Yamamoto). Applicants respectively traverse this rejection.

Claims 1, 2, 4, 6-8, 12, 13, 18, 32, 34, 36, 37, 39, and 41-46 have been amended to change "vibration sensing means" and "position sensing means" to "vibration sensor" and "position sensor," respectively.

The Examiner states that "Yamamoto teaches a system for monitoring a patient comprising a vibration sensing means (microphone) 3 for collecting tracheal vibration information from [sic] the patient and position sensing means . . ." (Office Action, p. 5). Applicants respectfully submit that Yamamoto fails to anticipate the present invention.

Yamamoto teaches a system for monitoring a patient that includes a vibration sensor (microphone 3 in Fig. 1) and a posture detection unit 7 (Fig. 4). Posture detection unit 7 has rotational position sensors 71a and 71b (Fig. 6a) within housing 51 (Fig. 4 and Col. 7 lines 10-15). Relay cable 12 and relay unit 6 are not components of position sensors 71a and 71b. Housing 51 also contains breathing effort detection unit 5 (Col. 7 lines 13-15).

Yamamoto teaches that microphone 3 is located in the test subject's neck area (Fig. 1) and that housing 51 (containing position sensors 71a and 71b as noted above) is located on belts 52 and 53 fitted onto the test subject's chest (Fig. 1 and Col. 5 lines 23-40). Fig. 1 teaches placement of belts 52 and 53 inferior to the level of the test subject's axillae (i.e. below armpit level).

Given the sites, noted above, of microphone 3 and position sensors 71a and 71b in Yamamoto, it is apparent that no portion of position sensors 71a and 71b is substantially adjacent to a portion of microphone 3.

Nothing in Yamamoto teaches placement of position sensors 71a and 71b superior to the level of the test subject's axillae. In fact, Yamamoto teaches the fitting of effort

detection unit 5 (and, therefore, position sensors 71a and 71b) to the test subject's abdomen (Col. 5 lines 9-10), which is the opposite direction from microphone 3 and thus teaches away from the invention of the applicants.

Furthermore, it is completely impractical for position sensors 71a and 71b to be located superior to the level of the axillae in the invention of Yamamoto, as follows. Belts 52 and 53 are intended to measure changes of the chest's circumference during respiration (Col. 5 lines 31-34). Positioning said belts superior to the axillae would necessitate placing them around the upper arms, resulting in measurement primarily of arm motion rather than chest expansion.

Thus, it is clear that Yamamoto does not teach substantially adjacent sensors as required by claim 1. Accordingly, it is respectfully submitted that claim 1 is allowable over Yamamoto.

Having overcome the rejection of claim 1 based on Yamamoto, it is respectfully submitted that the rejections of dependent claims 2, 4-13, 15-19, 21, 29, 31-37, 39-47, 49, and 50 are also overcome.

35 U.S.C. § 102(b) Rejections per Yamamoto

Claims 1-4, 6-9, 12, 15, 17-19, and 29 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,263,491 to Thornton (hereinafter referred to as Thornton). Applicants respectfully traverse this rejection.

The Examiner contends that Thornton “teaches a system for monitoring a patient comprising a vibration sensing means (microphone) M1 for collecting tracheal vibration information from a patient and a position sensing means 16, SW1, SW2 . . . , at least a

portion of which is substantially adjacent to a portion of the vibration sensing means.”

(Office Action, p. 8.) Applicants respectfully submit that Thornton fails to anticipate the present invention.

Nowhere does Thornton teach the detection or use of "tracheal vibration information." Instead, Thornton teaches a "mastication microphone" M1 (Fig. 1) mounted over the masseter (jaw) muscle (Col. 2 lines 64-66; Col. 6 lines 26-28) to pick up sounds made by contraction of the masseter muscle during chewing motions (Col. 6 lines 32-35).

Thornton does not teach that mastication microphone M1 is capable of detecting tracheal vibration. Furthermore, there is nothing in Thornton to suggest application of the invention to tracheal sound processing. In fact, locating microphone M1 over the masseter muscle all but insures it will be unable to detect tracheal vibrations associated with quiet respiration. In addition, Thornton teaches sending the output of microphone M1 through a 5-30 Hz bandpass filter F3 (Fig. 2") (apparently the same as filter F1 in Col. 6 line 35). This passband is far below the range of frequencies associated with respiratory-related tracheal sound. Thus, Thornton actually teaches away from the present invention.

Thus, it is apparent that Thornton does not teach collecting tracheal vibration information as required by claim 1. Accordingly, it is respectfully submitted that claim 1 is allowable over Thornton.

Having overcome the rejection of claim 1, it is respectfully submitted that the rejections of dependent claims 2-4, 6-9, 12, 15, 17-19, and 29 are also overcome.

35 U.S.C. § 102(b) Rejections per Griebel

Claims 1, 2, 4, 5, 12-14, 17-19, 21, 25, and 30 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,275,159 to Griebel (hereinafter referred to as Griebel). Applicants respectively traverse this rejection.

Claims 1, 2, 4, 12, 13, and 18 have been amended to change "vibration sensing means" and "position sensing means" to "vibration sensor" and "position sensor," respectively.

The Examiner contends that Griebel "discloses a system for monitoring a patient comprising a vibration sensing means (microphone) 4, 16, 17 for collecting tracheal vibration information from the patient and a position sensing means 6, 22 . . . , at least a portion of which is substantially adjacent to a portion of the vibration sensing means." (Office Action, p. 8.) Applicants respectfully submit that Griebel fails to anticipate the present invention.

Griebel teaches a vibration sensor (microphone 4 in Figs 1, 2 and 5) and a position detector 6 (Figs. 1, 2, and 5; Col. 5 lines 24-25). Vibration sensor (microphone 4) does not include amplifier 16 or filter 17 (Fig. 5; Col. 6 lines 37-57). Position detector 6 does not include position analyzer 22 (Fig. 5; Col. 7 lines 10-13).

Griebel teaches that microphone 4 is located against the test subject's larynx (Col. 5 lines 32-35) and that position detector 6 is located on the test subject's chest (inferior to the level of the axillae, as in Yamamoto) (Fig. 2). These locations are not substantially adjacent and, furthermore, it is apparent that no portion of position sensor 6 is substantially adjacent to a portion of microphone 4.

Griebel additionally teaches that position detector 6 may be fastened to the "upper body" of the test subject (Col. 6 lines 5-8). As shown in Fig. 2, "upper body" refers to the

specific region disclosed as the site for position detector 6. Griebel states that Fig. 2 shows "how the pickups are positioned on the body of the patient" (Col. 5 lines 27-28). Thus, it is apparent that Griebel did not have in mind that position detector 6 could be applied beyond the chest and so did not anticipate position detector 6 being substantially adjacent to microphone 4.

In fact, Griebel teaches away from placing position detector 6 substantially adjacent to microphone 4. As noted, Griebel teaches microphone 4 is situated over the larynx. In persons with long necks the position of the larynx does not necessarily reflect the position of the trunk of the body, owing to the mobility of the neck. Griebel further teaches that the purpose of position detector 6 is to measure the position of the body (Col. 7 lines 19, 58; Col. 9 lines 6, 15). Thus, placing position detector 6 substantially adjacent to laryngeal microphone 4 would poorly measure the position of the body, thereby impairing the stated purpose of position detector 6.

It is clear that placing position detector 6 substantially adjacent to microphone 4 is neither taught nor suggested by Griebel. Thus, Griebel did not teach substantially adjacent sensors as required by claim 1. Accordingly, it is respectfully submitted that claim 1 is allowable over Griebel.

Having overcome the rejection of claim 1, it is respectfully submitted that the rejections of dependent claims 2, 4, 5, 12-14, 17-19, 21, 25, and 30 are also overcome.

35 U.S.C. § 103(a) Rejections per Yamamoto in view of Macklem

Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,241,683 to

Macklem et al (hereinafter referred to as Macklem). Applicants respectively traverse this rejection.

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to use the sampling rate of Macklem in the system of Yamamoto.” (Office Action, p. 12-13.) However, even if such a combination was obvious, it would not result in claim 20.

As above, the present invention is not anticipated by Yamamoto. Yamamoto does not teach or suggest a position sensor substantially adjacent to a vibration sensor. In addition, nothing in Macklem teaches or suggests a position sensor substantially adjacent to a vibration sensor. In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of a sampling rate by Macklem still fails to render the present invention obvious.

The Examiner’s discussion fails to evidence the recited limitations of claim 20, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claim 20 and the Examiner’s rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

35 U.S.C. § 103(a) Rejections per Yamamoto in view of Sackner

Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,551,252 to

Sackner et al (hereinafter referred to as Sackner). Applicants respectively traverse this rejection.

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to use a memory capable of storing 128 MB of data in the system of Yamamoto.” (Office Action, p. 13.) However, even if such a combination was obvious, it would not result in claim 22.

As above, the present invention is not anticipated by Yamamoto. Yamamoto does not teach or suggest a position sensor substantially adjacent to a vibration sensor. In addition, nothing in Sackner teaches or suggests a position sensor substantially adjacent to a vibration sensor. In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of a memory size by Sackner still fails to render the present invention obvious.

The Examiner’s discussion fails to evidence the recited limitations of claim 22, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claim 22 and the Examiner’s rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

35 U.S.C. § 103(a) Rejections per Yamamoto in view of Nissila

Claims 24 and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,432,061 to

Nissila et al (hereinafter referred to as Nissila). Applicants respectively traverse this rejection.

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to use a wireless connection, as described by Nissila in place of the wired connection between the sensing means and recording means of Yamamoto.” (Office Action, p. 14.) However, even if such a combination was obvious, it would not result in claims 24 and 52.

As above, the present invention is not anticipated by Yamamoto. Yamamoto does not teach or suggest a position sensor substantially adjacent to a vibration sensor. In addition, nothing in Nissila teaches or suggests a position sensor substantially adjacent to a vibration sensor. In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of a wireless connection by Nissila still fails to render the present invention obvious.

The Examiner’s discussion fails to evidence the recited limitations of claims 24 and 52, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claims 24 and 52 and the Examiner’s rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

35 U.S.C. § 103(a) Rejections per Yamamoto in view of Gavriely

Claims 23 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,168,568 to

Gavriely (hereinafter referred to as Gavriely). Applicants respectively traverse this rejection.

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to use a wireless receiver and transmitter in place of the wired connection of Yamamoto.” (Office Action, p. 14.) However, even if such a combination was obvious, it would not result in claims 23 and 51.

As above, the present invention is not anticipated by Yamamoto. Yamamoto does not teach or suggest a position sensor substantially adjacent to a vibration sensor. In addition, nothing in Gavriely teaches or suggests a position sensor substantially adjacent to a vibration sensor. In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of a wireless microphone by Gavriely still fails to render the present invention obvious.

The Examiner’s discussion fails to evidence the recited limitations of claims 23 and 51, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claims 23 and 51 and the Examiner’s rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

35 U.S.C. § 103(a) Rejections per Yamamoto in view of Gavriely

Claims 26-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,168,568 to Gavriely. Applicants respectively traverse this rejection.

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of the invention to use the microphone of Gavriely as that of Yamamoto.” (Office Action, p. 15.) However, even if such a combination was obvious, it would not result in claims 26-28.

As above, the present invention is not anticipated by Yamamoto. Yamamoto does not teach or suggest a position sensor substantially adjacent to a vibration sensor. In addition, nothing in Gavriely teaches or suggests a position sensor substantially adjacent to a vibration sensor. In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of a frequency range and a playback means by Gavriely still fails to render the present invention obvious.

The Examiner’s discussion fails to evidence the recited limitations of claims 26-28, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claims 26-28 and the Examiner’s rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

35 U.S.C. § 103(a) Rejections per Karakasoglu in view of Thornton

Claims 38 and 41-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over US Patent No. 6,171,258 to Karakasoglu et al (hereinafter referred to as Karakasoglu) in view of Thornton. Applicants respectively traverse this rejection.

The Examiner states that "Karakasoglu teaches a method for monitoring a patient wherein tracheal vibration information is collected from a patient at a location on the patient's body by coupling a vibration sensing means to the patient . . . and information indicative of the orientation of the patient's body is obtained substantially adjacent to the location at which the tracheal vibration information is collected . . . Thornton . . . teaches a position sensing means comprising an accelerometer 16 and gravity sensing switches SW1 and SW2 . . . it would have been obvious to one of ordinary skill in the art at the time of the invention to use the position sensing means of Thornton '491 as that of Karaksoglu [sic]." (Office Action, p. 16.) However, even if such a combination was obvious, it would not result in claims 38 and 41-43.

Karakasoglu teaches a body position sensor S7 "that can be located in an appropriate position as for example the chest or a thigh or torso of the patient" or in "an alternative position such as the head of the patient" (Col. 5 lines 28-34). Karakasoglu additionally teaches a vibration sensor S8 "in close proximity to the trachea, as for example on the neck" (Col. 5 lines 34-37). Thus, there is nothing in Karakasoglu that teaches or suggests a position sensor substantially adjacent to a tracheal vibration sensor and, in fact, he teaches away from it. The Examiner's citation of Figures 1 and 2 does not contradict the clear language of the specification, as they clearly show separate portions of the patient's body, and do not indicate that the position sensor is located near the vibration sensor.

As above, the present invention is not anticipated by Thornton. Thornton does not teach or suggest a position sensor substantially adjacent to a vibration sensor.

In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of a position sensing means comprising an accelerometer and gravity sensing switches by Thornton still fails to render the present invention obvious.

The Examiner's discussion fails to evidence the recited limitations of claims 38 and 41-43, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claims 38 and 41-43 and the Examiner's rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

35 U.S.C. § 103(a) Rejections per Yamamoto in view of Hatlesad

Claim 48 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto, as discussed above, and further in view of US Patent No. 6,949,475 to Hatlesad (hereinafter referred to as Hatlesad). Applicants respectfully traverse this rejection.

The Examiner states that "it would have been obvious to one of ordinary skill in the art at the time of the invention to use an accelerometer as the first gravity sensing device in place of the tilt sensor of Yamamoto." (Office Action, p. 17.) However, even if such a combination was obvious, it would not result in claim 48.

As above, the present invention is not anticipated by Yamamoto. Yamamoto does not teach or suggest a position sensor substantially adjacent to a vibration sensor. In addition, nothing in Hatlesad teaches or suggests a position sensor substantially adjacent

to a vibration sensor. In the absence of any suggestion in the cited art to locate the position sensor substantially adjacent to the vibration sensor, the teaching of an accelerometer as a gravity sensing device by Hatlesad still fails to render the present invention obvious.

The Examiner's discussion fails to evidence the recited limitations of claim 48, specifically locating the position sensor substantially adjacent to a vibration sensor. See *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). As such, a *prima facie* case of obviousness does not exist with regard to claim 48 and the Examiner's rejection is overcome. See MPEP § 2143. Applicants thus respectfully request reconsideration of this rejection.

The other prior art cited by the Examiner has been considered. No response is deemed necessary.

CONCLUSION

The Applicant respectfully requests the entry of the amendments to the specification and drawings as these amendments do not enter new subject matter into the disclosure.

The Applicant contends that the Examiner's 35 U.S.C. § 101 rejection has been overcome by the changes made to the claims as requested by the Examiner.

The Applicant contends that the Examiner's 35 U.S.C. § 102(b) and § 102(e) rejections based on Yamamoto, Thornton and Griebel are overcome in that none of these references teach each and every limitation of the presently claimed invention.

The Applicant finally contends that the Examiner's 35 U.S.C. § 103 rejections are overcome in that a *prima facie* case of obviousness has not been made as none of the cited combinations teach or suggest an essential limitation of the presently claimed invention..

All dependent claims of the present application are allowable by virtue of their dependence on (either directly or via an intermediate dependent claim) an allowable base claim.

While the Applicant believes a *Notice of Allowance* is now warranted, the Examiner is invited to contact the Applicant or Kenneth M. Kaslow, Esq. with any questions concerning the present application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John Sotos". The signature is fluid and cursive, with the first name "John" and last name "Sotos" clearly distinguishable.

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